

## § 113.452

which will protect the test animal the same as the Standard Toxin-Antitoxin mixture. Test animals dying sooner than the controls indicate the unit value selected in that dilution was not present, whereas those living longer indicate a greater unit value.

[39 FR 16859, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974, and amended at 40 FR 760, Jan. 3, 1975; 40 FR 41996, Sept. 10, 1975; 43 FR 1479, Jan. 10, 1978; 50 FR 24905, June 14, 1985. Redesignated at 55 FR 35561, Aug. 31, 1990; 61 FR 51776, Oct. 4, 1996; 64 FR 43045, Aug. 9, 1999]

### § 113.452 *Erysipelothrix Rhusiopathiae* Antibody.

*Erysipelothrix Rhusiopathiae* Antibody is a specific antibody product containing antibodies directed against one or more somatic antigens of *Erysipelothrix rhusiopathiae*. Each serial shall be tested as provided in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Each serial shall meet the applicable general requirements provided in § 113.450.

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested using the two-stage test provided in this section.

(1) In the first stage, each of 40 Swiss mice, each weighing 16 to 20 grams, shall be injected subcutaneously with 0.1 ml of product (dried product shall be rehydrated according to label directions). Twenty-four hours postinjection, the injected mice and 10 additional mice designated controls shall be challenged subcutaneously with the same culture of *Erysipelothrix rhusiopathiae*.

(2) If less than eight of the 10 controls die from erysipelas within 7 days post-challenge, the test is invalid. All dead mice shall be examined to determine if the cause of death was *Erysipelothrix rhusiopathiae* infection.

(3) The mice injected with product shall be observed for 10 days postchallenge and all deaths recorded. The second stage shall be required when 7-10 of the mice injected with product die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

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(4) The results of the test shall be evaluated according to the following table:

Stage	Number of vaccines	Cumulative number of vaccines	Cumulative total number of deaths for a satisfactory test	Cumulative total number of deaths for an unsatisfactory test
1	40	40	6 or less	11 or more.
2	40	80	12 or less	13 or more.

[39 FR 16859, May 10, 1974. Redesignated at 39 FR 25463, July 11, 1974, as amended at 40 FR 20067, May 8, 1975; 40 FR 23989, June 4, 1975. Redesignated at 55 FR 35561, Aug. 31, 1990; 61 FR 51776, Oct. 4, 1996; 64 FR 43045, Aug. 9, 1999]

### § 113.453 [Reserved]

### § 113.454 *Clostridium Perfringens* Type C Antitoxin.

*Clostridium Perfringens* Type C Antitoxin is a specific antibody product containing antibodies directed against the toxin of *Clostridium perfringens* Type C. Each serial shall be tested as provided in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Each serial shall meet the applicable general requirements provided in § 113.450.

(b) *Potency test.* Bulk or final container samples of completed product from each serial shall be tested using the toxin-neutralization test for Beta Antitoxin provided in this section. Dried products shall be rehydrated according to label directions.

(1) When used in this test, the following words and terms shall mean:

(i) *International antitoxin unit.* (I.U.) That quantity of Beta Antitoxin which reacts with  $L_0$  and  $L_+$  doses of Standard Toxin according to their definitions.

(ii)  *$L_0$  dose.* The largest quantity of toxin which can be mixed with one unit of Standard Antitoxin and not cause sickness or death in injected mice.

(iii)  *$L_+$  dose.* The smallest quantity of toxin which can be mixed with one unit of Standard Antitoxin and cause death in at least 80 percent of injected mice.